TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	880	1	880	10	8,800

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
806.20	440	1	440	10	4,400

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection requirements in part 806 prior to the direct final rule (63 FR 42229) have been approved by OMB and assigned control number 0910–0359. When preparing the earlier package for approval of the information collection requirements in part 806, FDA reviewed the reports of corrections and removals submitted in the previous 3 years under 21 CFR part 7 (the agency's recall provisions). During that period of time, no reports of corrections or removals were submitted by distributors. For that reason, FDA did not include distributors among the respondents estimated in the collection burden for the requirements previously approved by OMB. Because distributors were not included in that earlier estimate and because FDAMA now has eliminated requirements for distributor reporting, FDA has determined that estimates of the reporting burden for §§ 806.10 and 806.20 should remain the same.

Dated: November 17, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–31411 Filed 11–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0791]

Determination of Regulatory Review Period for Purposes of Patent Extension; Tisseel VH Kit

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Tisseel VH Kit and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product Tisseel VH Kit. Tisseel VH Kit is indicated for use as an adjunct to hemostasis in surgeries involving cardiopulmonary bypass and treatment of splenic injuries due to blunt or penetrating trauma to the abdomen, when control of bleeding by conventional surgical techniques, including suture, ligature, and cautery is ineffective or impractical, and also as an adjunct for the closure of colostomies. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Tisseel VH Kit (U.S. Patent No. 4,362,567) from Immuno Aktiengesellschaft fur chemsih-medizinshe Produkte, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 7, 1998, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of Tisseel VH Kit represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Tisseel VH Kit is 5,065 days. Of this time, 1,203 days occurred during the testing phase of the regulatory review

period, while 3,862 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 351 of the Public Health Service Act became effective*: June 20, 1984. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 20, 1984.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act*: October 5, 1987. FDA has verified the applicant's claim that the product license application (PLA) for Tisseel VH Kit (PLA 87-0509) was initially submitted on October 5, 1987.

3. *The date the application was approved*: May 1, 1998. FDA has verified the applicant's claim that PLA 87-0509 was approved on May 1, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,827 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 25, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before May 24, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 4, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98-31413 Filed 11-24-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98C-1017]

International Association of Color Manufacturers; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the International Association of Color Manufacturers has filed a petition proposing that the color additive regulations be amended to provide for the safe use of D&C Red No. 28 and its aluminum lake to color food and dietary supplements.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3071.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 9C0264) has been filed by the International Association of Color Manufacturers, c/o Daniel R. Thompson, P.C., 1620 I St., suite 925, Washington, DC 20006. The petition proposes to amend the color additive regulations to provide for the safe use of D&C Red No. 28 and its aluminum lake to color food and dietary supplements.

The agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 6, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98-31505 Filed 11-24-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-1002]

Center for Biologics Evaluation and Research Medical Device Action Plan; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of November 2, 1998 (63 FR 58743). The document announced an upcoming public meeting requesting suggestions for improvements to the Center for Biologics Evaluation and Research's regulation of medical devices or reasons to maintain the current systems to protect public health. The notice inadvertently omitted the date and addresses for the submissions of comments after the meeting. This document corrects those omissions.

FOR FURTHER INFORMATION CONTACT: Kathy A. Eberhart, Center for Biologics Evaluation and Research (HFM-43), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-1317.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 2, 1998 (63 FR 58743), in FR Doc. 98-29185, FDA announced an upcoming public meeting requesting suggestions for improvements to the the Center for Biologics Evaluation and Research's regulations of medical devices or reasons to maintain the current systems to protect public health. The notice inadvertently omitted the date and address for the submissions of comments after the meeting.

1. On page 58743, in the third column, under the *Date and Time* caption, a second sentence is added to read "Submit written comments by December 22, 1998."

2. On the same page, after the "*Location*" portion, another paragraph is added to read "*Addresses*: Submit by December 22, 1998, written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy and received comments are available for public